

103



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,885	11/21/2003	Ry Wagner	1505-67088	3269

7590 08/09/2004

KLARQUIST SPARKMAN, LLP
One World Trade Center
Suite 1600
121 S.W. Salmon Street
Portland, OR 97204

EXAMINER

GARVEY, TARA L

ART UNIT	PAPER NUMBER
----------	--------------

1636

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,885	WAGNER ET AL.	
	Examiner	Art Unit	
	Tara L Garvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 20, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1, 7-13 and 15 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 is/are allowed.
- 6) ☒ Claim(s) 1-6, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-15 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 12 and 13 only as drawn to SEQ ID No.2, 2-6 and 14 drawn to the purified protein of SEQ ID No. 2, variants of SEQ ID No. 2 and the purified protein bound by a specific binding agent classified in class 530, subclass 350.
- II. Claims 1, 12 and 13 only as drawn to SEQ ID No. 13, 7-11 and 15 drawn to the purified protein of SEQ ID No. 13, variants of SEQ ID No. 13 and the purified protein bound by a specific binding agent classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

The polypeptides of Group I and Group II are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other group. Therefore, the inventions of the groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Anne Carlson on July 23, 2004 a provisional election was made without traverse to prosecute the invention of Group I,

Art Unit: 1636

claims 1, 12 and 13 only as drawn to SEQ ID No. 2, 2-6 and 14. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1, 12 and 13 only as drawn to SEQ ID No. 13, 7-11 and 15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Please update the first paragraph of the specification in which priority is claimed to Application No. 09/746,801. Please indicate that this application is now Patent No. 6,689,940.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to the amino acid sequence of SEQ ID No.2 which has ELF3 protein biological activity, variants of SEQ ID No. 2 and homologs of SEQ ID No. 2 having at least 91% identity. Claim 2 is drawn to the amino acid sequence of SEQ ID No. 2. Claim 3 limits the invention to an amino acid sequence of SEQ ID No. 2 that varies by one or more amino acids. Claim 4 limits the invention to an amino acid sequence having at least 91% identity to SEQ ID No. 2. Claim 5 limits the invention to an amino acid sequence having at least 93% identity to SEQ ID No. 2. Claim 6 limits the invention to an amino acid sequence having at least 95% identity to SEQ ID No. 2. Claim 12 limits the invention to the purified protein of claim 1 bound by a specific binding agent. Claim 13 limits the invention to the purified protein of claim 1 bound by an anti-ELF3 protein antibody.

While the specification describes SEQ ID No. 2, the recitation of one or more conserved amino acid changes and percent identity allows for polypeptides with altered sequence with regard to SEQ ID No. 2 and thus broadly encompasses variants and homologs of SEQ ID No. 2. While the specification does teach that the polypeptide of SEQ ID No. 2 can be altered by substituting one or more amino acids, the specification does not teach any altered sequences that have ELF3 biological activity. Further, neither the specification nor the claims place a specific limit on the number of amino acid substitutions that may be made to SEQ ID No. 2 and does not teach which amino

Art Unit: 1636

acids can be altered to result in a protein with ELF3 biological activity. The specification teaches homologs of SEQ ID No. 2, but does not describe the percent identity to the claimed amino acid sequence or show the biological activity exhibited by these homologs. The recitation of SEQ ID No. 2 is not representative of this broad genus of variants and homologs of SEQ ID No. 2.

The prior art does not appear to offset the deficiencies in the specification in that it does not describe all the variants and homologs with greater than 91% identity to SEQ ID No. 2 or the function of these polypeptides.

Therefore, there is no structural and functional basis provided by the prior art or the instant specification for one of skill in the art to envision the broad genus of variants and homologs of the amino acid sequence of SEQ ID No. 2 that retain ELF3 biological activity. A single full-length protein sequence of SEQ ID No. 2 is not representative of the functionally different or equivalent proteins from this broad class. One of skill in the art would not have been able to envision a representative number of variants and homologs with ELF3 biological activity to sufficiently describe the broad genus of variations of SEQ ID No. 2 to encompass the rejected claims. One of skill in the art would have thus reasonably concluded that the applicants were not in possession of the claimed invention for claims 1-6, 12 and 13.

Claim 12 is drawn to the protein of SEQ ID No.2 bound to an ELF3 specific binding agent. The specification does not describe the structure of all possible binding agents. The specification describes that an ELF3 specific binding agent is one that binds substantially to only the ELF3 protein, but the specification only teaches that one

of the agents is an anti-ELF3 antibody. The prior art does not offset the lack of description in the specification in that it does not describe structures for all of the possible binding agents. Therefore, there is not a structural and functional basis provided by the prior art or the specification for one of skill in the art to envision all the structures of possible ELF3 binding agents. One of skill in the art would have concluded that the applicants were not in possession of the claimed invention for claim 12.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara L Garvey whose telephone number is (571) 272-2917. The examiner can normally be reached on Monday through Friday 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling


Art Unit: 1636

please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tara L Garvey
Examiner
Art Unit 1636

TLG



JAMES KETTER
PRIMARY EXAMINER